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OCT 3 0 2007

Attachment B. 510(k) Summary

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510K Summary

Date of Submission: **July 24, 2007**

Contact:

Amy Jones
National Marketing Manager
TriE Medical, Inc.
120 Southcenter Ct, Suite 400
Morrisville, NC 27560
(919) 388-3360 (office)
ajones@triemedical.com

Proprietary Name: Bilibee LED Phototherapy System

Common Usual / Name: Neonatal Phototherapy Device

Device Classification Name: Unit, Neonatal Phototherapy

Classification Reference: 21 CFR 880.5700

Classification: Class II

Appropriate Classification Panel: General Hospital

Product Code: LBI

Predicated Devices: Natus Medical, Inc. neoBLUE™ LED Phototherapy System (K022196)

Respironics Wallaby®3 Phototherapy System (K991627)

Medela, Inc. Bilibed® Phototherapy Unit (K984589).

Reason for Submission: New Device

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Substantial Equivalence:
Medical Select believes that the *BiliBee LED Phototherapy System* is substantially equivalent to several legally marketed devices for the treatment of neonatal hyperbilirubinemia (jaundice) that use the same operating principle of delivery of light to degrade bilirubin and therefore does not raise any new safety concerns.

Intended Use:
The intended use of the *BiliBee LED Phototherapy System* is the treatment of infants diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The system can be used with off-the-shelf AA battery pack for portability or an AC/DC regulated power supply. The *BiliBee LED Phototherapy System* can be used in a hospital or at home.

Device Description:
The *BiliBee LED Phototherapy System* is both a battery-operated device or AC/DC regulated power that provides therapeutic light through an LED illuminator panel for the treatment of neonatal jaundice (hyperbilirubinemia). Treatment is applied by placing the patient (neonate) on the *BiliBee LED Phototherapy System* panel with a disposable sheath separating the child from the panel's surface. The patient's eyes do not need to be covered during treatment. Treatment is intended to be applied 24 hours a day until the bilirubin levels have dropped sufficiently that the child no longer suffers from jaundice. Treatment time is expected to range from 3 days to 3 weeks. Phototherapy treatment of neonatal jaundice using the BiliBee LED Phototherapy System can be applied at home or in a hospital.

BiliBee LED Phototherapy System Physical Characteristics:

overall dimensions	width ~ 4", length ~ 8", thickness ~ 0.4"
treatment area	width = 4", length = 6"
weight	light panel < 0.5 lb. battery pack < 1 lb.
power source	removable rechargeable 6V battery. (Note that two batteries are provided so that one can be recharged while the other is in use).
control mechanism	solid state electronics
light source	Flexible LED (Light Emitting Diode) array emitting blue light @ 470nm. Distance between LEDs is .25" to 0.5", depending on flexing.
light output	60μW/nm/cm^2 (maximum)
alarms	audible low battery warning

Disposable Barrier (Sheath)
The disposable sheath consists of two pieces of synthetic woven fabric sewn together on 3 of 4 sides. It is designed to slide over the BiliBee LED Phototherapy System like a sock to serve as a barrier between the patient and the flexible LED array during treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 9 2007

Medical Select, Incorporated
C/O Ms. Amy Jones
National Marketing Manager/ Regulatory Affairs
TriE Medical, Incorporated
120 Southcenter Court, Suite 400
Morrisville, North Carolina 27560

Re: K072097
Trade/Device Name: Bilibee LED Phototherapy System
Regulation Number: 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: July 24, 2007
Received: July 31, 2007

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A. Indications for Use Statement

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INDICATIONS FOR USE STATEMENT

The intended use of the BiliBee LED Phototherapy System is the treatment of infants diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The system can be used with off-the-self AA battery pack for portability or an AC/DC regulated power supply. The BiliBee LED Phototherapy System can be used in a hospital or at home

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K073497